

Application Number 10/731,881

Amendment in response to the Office Action mailed May 24, 2007

### **REMARKS**

This Amendment is responsive to the Office Action dated May 24, 2007. Applicant has amended claims 1, 6, 19, 25, and 28, and added claims 29-32. Claims 1, 2, 4-20, 22-25, and 28-32 are pending.

### **Allowable Subject Matter**

The Office Action indicated that claims 15-17 and 23 are allowable in their present form, and objected to claims 11-14 as including subject matter that would be allowable if rewritten in independent form.

### **Amendments to the Specification**

The Office Action objected to the amendments to paragraph [0002] of Applicant's specification submitted in Applicant's previous response to the Office Action mailed on December 11, 2006 because the amendments to the specification denoted paragraph [0002] as beginning on page 2 of Applicant's originally filed disclosure, whereas paragraph [0002] begins on page 1. With the present Amendment, Applicant has corrected the amendment to paragraph [0002] to correctly denote that paragraph [0002] begins on page 1, line 20. Withdrawal of the objection to the amendment to the specification is respectfully requested.

Applicant has also amended paragraph [0035] of the originally filed disclosure to add description of the housing of the control module 210. By these amendments, Applicant provides additional support in the written description for new claims 30-32. No new matter has been added by way of the amendment to paragraph [0035]. Support for the amendments to paragraph [0035] can be found at paragraph [0048] of U.S. Patent Application Serial No. 10/731,869, entitled "MODULAR IMPLANTABLE MEDICAL DEVICE," to Wahlstrand et al., which was incorporated by reference in its entirety in Applicant's originally filed disclosure.

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### **Claim Objections**

The Office Action also objected to claims 1 and 19 because of apparent inadvertent typographical errors. The Office Action appeared to be referring to the language, "wherein at least one of the second and third components at least one of comprises or is coupled to . . ." However, the aforementioned language was not an inadvertent typographical error. Rather, the language is intended to convey that of the second and third components, at least one comprises, is coupled or both comprises and is coupled to the motion reduction element or the means within the overmold for reducing relative motion between at least two modules.

In order to expedite prosecution, Applicant has amended claims 1 and 19 to recite, "wherein at least one of the second or third components comprises or is coupled to . . .," with the understanding that the intended scope of claims 1 and 19 has not changed.

### **Claim Rejection Under 35 U.S.C. §§ 102(b), 102(e), and 103(a)**

In the Office Action, claims 1, 2, 4, 5, 7, 9, 18-20, 22, 24, 25, and 28 were rejected under 35 U.S.C. § 102(b) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281, "Berrang"). In addition, claims 8 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang. Claims 1-2, 4, 6, 18-20, 22 and 24 were rejected under 35 U.S.C. § 102(e) as being anticipated by Engmark et al. (U.S. Patent Application Publication No. 2004/0082977, "Engmark"). Claims 5 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engmark.

Applicant respectfully traverses the rejection of the claims. Berrang and Engmark fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. §§ 102(b), 102(e), and 103(a), and provide no teaching that would have suggested the desirability of modification to include such features. Furthermore, as provided below, Engmark is disqualified under 35 U.S.C. § 103(c) from being used in a rejection under 35 U.S.C. § 103(a).

### **Berrang**

In support of the rejection of independent claims 1, 19, 25, and 28, the Office Action characterized housing sections 2 and 3, shown in FIGS. 2 and 3 of Berrang, as two interconnected modules, epoxy 28, 31 as housings of the sections 2 and 3, and "a component of

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palladium, a component of gold and a component of titanium/platinum/medical grade silicone” as an overmold that at least partially encapsulates the epoxy 28, 31 and is located adjacent to at least one side surface of the housings.<sup>1</sup> In addition, the Office Action characterized the bridge structure 6 in Berrang as a motion reduction element.<sup>2</sup> Applicant respectfully disagrees with the Office Action’s interpretation of Berrang, and submits that Berrang does not disclose or suggest each and every element of independent claims 1, 19, 25 or 28.

For example, Berrang does not disclose a plurality of interconnected modules comprising a respective housing and an overmold that at least partially encapsulates each of the housings. Berrang’s disclosure clearly and repeatedly describes its device as having a single housing (“the housing”) comprising two sections 2 and 3.<sup>3</sup> At no time does Berrang teach or even suggest that its device includes a plurality of interconnected modules that each comprise a respective housing to house the respective module, much less an overmold that at least partially encapsulates the housings, as recited by Applicant’s independent claims 1, 19, 25, and 28 as amended. Furthermore, Berrang fails to disclose or suggest an overmold comprising second and third components that are located adjacent to at least one side surface of a respective one of the housings of the modules, as recited by claims 1 and 19.

As described at column 11, lines 60-63 of Berrang’s disclosure, medical grade epoxy (or any biocompatible polymer) 28 is used to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of housing sections 2 and 3. Berrang clearly teaches that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.<sup>4</sup> Thus, the epoxy surfaces are not housings for housing sections 2 and 3, as the Office Action indicated, because the epoxy surfaces in no way house housing sections 2 and 3 as required by a housing, and as explicitly required by Applicant’s independent claims. Applicant has amended the independent claims to clarify that each of the modules comprises a housing to house the respective module, rather than merely being a component of the module. In contrast, the epoxy surfaces in Berrang are merely components of housing sections 2 and 3.

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<sup>1</sup> Office Action at page 4, item 13.

<sup>2</sup> *Id.*

<sup>3</sup> Berrang, columns 3-4, lines 25-4 and column 9, lines 51-62.

<sup>4</sup> *Id.*

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The Office Action found that column 12, lines 20-25 of Berrang describes an overmold that at least partially encapsulates the epoxy 28, 31, and that the overmold is located adjacent to at least one side surface of the epoxy 28, 31. Applicant respectfully disagrees, and submits that the Office Action has misinterpreted the scope and content of Berrang, as well as Applicant's claims 1 and 19. At column 12, lines 20-25, Berrang teaches that the epoxy surfaces 28 and 31 are covered with a gold layer, which is designed to bond directly to the outside edge of the ceramic substrates 24 and 25, thus creating a sealed, hermetic covering over the components mounted onto each of the ceramic substrates 24 and 25. FIG. 2 illustrates a gold foil 27 surrounding the entire Berrang device. This layer of gold is not an overmold, as suggested by the Office Action. Instead, the gold layer forms a single housing for housing sections 2 and 3, and sections 2 and 3 are two sections within the single housing.<sup>5</sup>

Nothing in Berrang teaches or suggests that housing sections 2 and 3 are enclosed in a housing other than the gold layer so as to be considered modules each comprising a housing. Furthermore, because the gold layer is the housing for housing sections 2 and 3, which the Office Action characterized as "modules," the gold layer cannot be an overmold that at least partially encapsulates each of the housings of the at least two interconnected modules, as required by claims 1 and 16.

Applicant's independent claim 1 and 19 recite an overmold that includes a first component that at least partially encapsulates each of the housings of interconnected modules, and second and third components that are located adjacent to at least one side surface of a respective one of the housings. The recitation of "respective," indicates that the second and third components are located adjacent to at least one side surface of different housings. For example, the second component of the overmold may be located adjacent to at least one side surface of a housing of a first module, and the third component may be located adjacent to at least one side surface of a housing of a second module that is different than the first module. The language of claims 1 and 19 is consistent with Applicant's disclosure. On the other hand, the gold layer of Berrang is a single component, and, accordingly, cannot be second and third components that are located adjacent to at least one side surface of a respective housing.

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<sup>5</sup> See *id.* at column 9, lines 58-62 and column 3, lines 32-35.

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In an alternative interpretation of Berrang, the Office Action characterized electronics 21 and battery 18 of Berrang as two modules, each with a respective housing at least partially encapsulated by an overmold.<sup>6</sup> The Office Action further stated that the electronics 21 are housed by support disc 33, the battery 18 necessarily includes a housing, and the epoxy 28, 31, gold layer, and “the outer coating of either titanium/platinum or medical grade silicone” are components of an overmold.<sup>7</sup> Applicant disagrees with the Office Action’s alternative interpretation of Berrang.

The alternative interpretation of Berrang also fails to render Applicant’s independent claims 1, 19, 25, and 28 unpatentable. As one example of the deficiencies evident in Berrang, Berrang does not disclose or suggest that support disc 33 provides a housing for electronics 21. Claims 1, 19, 25, and 28 explicitly state that the housing houses the respective module. On the other hand, the support disc 33 does not house the electronics 21, but, instead, provides a mounting surface for piezoceramics actuator 22. Berrang describes piezoceramic actuators 19 and 22 that are each preferably mounted to a flexible support disc 32 and 33, respectively.<sup>8</sup> Snap domes 20 and 23 may be pushed to cause piezoceramic actuators 19 and 22 on flexible support discs 32 and 33 to slightly bend thereby creating a voltage pulse sufficient to activate the electronics.<sup>9</sup> As illustrated in FIG. 2, support disc 33 is located proximate to one edge of electronics 21 but not the other surfaces of electronics 21. Thus, it is unclear how support disc 33 even houses electronics 21. Berrang fails to disclose or suggest a plurality of interconnected modules each comprising a housing to house the respective module, and, accordingly, fails to disclose or suggest the requirements of independent claims 1, 19, 25, and 28.

The alternative interpretation of Berrang provided by the Office Action also fails to disclose or suggest an overmold comprising a first component that at least partially encapsulates each of the housings of a plurality of interconnected modules, and second and third components that are located adjacent to at least one side surface of a respective one of the housings, as recited by claims 1 and 19. The Office Action characterized the “component of palladium, a component of gold and a component of titanium/platinum/medical grade silicone” as different components

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<sup>6</sup> Office Action at page 5, item 11.

<sup>7</sup> *Id.*

<sup>8</sup> Berrang, column 12, lines 32-35.

<sup>9</sup> *Id.* at 35-42.

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of an overmold, and reasoned that column 12, lines 20-25 of Berrang discloses an overmold in which those three components are located adjacent to at least one side surface of a respective one of the epoxy surfaces 28, 31.<sup>10</sup> The Office Action did not indicate which of those elements it considered to be the first, second or third components of the overmold.

Even if the deposited palladium, gold, and titanium/platinum/silicone layers on the epoxy surfaces 28, 31 of the Berrang device constitute an overmold and the epoxy surfaces 28, 31 constitute housings, both assumptions of which Applicant strongly disputes, Berrang does not describe or even suggest that the palladium, gold, and titanium/platinum/silicone layers are components that are located adjacent to a respective one of the epoxy surfaces. Instead, the palladium, gold, and titanium/platinum/silicone layers appear to cover both the epoxy surfaces 28, 31, rather than different epoxy surfaces 28, 31. Accordingly, Berrang cannot describe an overmold as recited in Applicant's claims 1 and 19.

Applicant's independent claim 25 recites, among other things, an implantable medical device that includes a plurality of interconnected modules each comprising a housing, an overmold that at least partially encapsulates each of the housings, a coupling module to couple at least two of the modules, and a motion reduction element within the overmold to reduce relative motion between the at least two of the modules. With respect to the rejection independent claim 25, the Office Action characterized the coil 4, battery 18 and electronics 21 as modules, and a "flexible tether" as a coupling module, and referred to FIGS. 1 and 15-18 and column 6, lines 4-25 of Berrang.<sup>11</sup> Applicant respectfully disagrees with the Office Action's conclusion of unpatentability of claim 25.

As described above, the battery 18 and electronics 21 are not modules that each comprise a housing. The coil 4 also fails to constitute a module comprising a housing. Berrang does not state that the coil 4 comprises a housing, and the Office Action's basis for finding the coil has a housing is unclear. While Berrang states the coil 4 includes "a number of turns of a biocompatible metal . . . encapsulated in a bioinert polymer carrier,"<sup>12</sup> Berrang fails to further provide that the coil 4 comprises a housing. The bioinert polymer carrier is the coil 4, and therefore, cannot be housing to house the coil.

<sup>10</sup> Office Action at page 5, item 11.

<sup>11</sup> *Id.* at page 6, item 14.

<sup>12</sup> Col. 6, ll. 6-10.

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In addition, Berrang fails to describe or even mention a "flexible tether." The Office Action relied on column 6, lines 4-25 of Berrang as describing a flexible tether. However, at the cited portion of Berrang, Berrang merely describes the coil and does not mention a "tether," or anything similar to a "tether." FIGS. 1 and 15-18 of Berrang also fail to indicate that the Berrang device necessarily includes a "flexible tether" that couples the coil to the battery 18 and electronics 21. Given the lack of support for the Office Action's finding that Berrang discloses a "flexible tether," as well as the lack of description in Berrang of any coupling module, Berrang cannot anticipate Applicant's independent claim 25.

Applicant's independent claim 28 is directed to an implantable medical device that includes a plurality of interconnected modules each comprising a housing, an overmold that at least partially encapsulates each of the housings, and a motion reduction element within the overmold to reduce relative motion between at least two of the modules. According to claim 28 as amended, the overmold comprises a first component comprising an elastomeric material and second and third components comprising nonelastomeric material, where the motion reduction element couples the second and third components. Support for the amendment to claim 28 is found throughout Applicant's originally filed disclosure, including at paragraph [0071].

Berrang fails to teach or suggest each and every element of Applicant's claim 28 as amended. Among other things, Berrang fails to disclose or suggest a plurality of interconnected modules each comprising a housing, an overmold comprising two components comprising a nonelastomeric material, and a motion reduction element that couples those components. As noted above, Applicant disagrees with the Office Action's characterization of the palladium, gold, and titanium/platinum/medical grade silicone layers as an overmold, and the characterization of the bridge 6 as a motion reduction element. In addition, Berrang does not disclose or suggest that the bridge 6 couples second and third components of an overmold. To the extent Berrang discloses the relationship between palladium, gold and titanium/platinum/medical grade silicone layers, Berrang states that "[t]he housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof."<sup>13</sup> This disclosure does not in any way suggest that the bridge couples two components of the overmold,

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<sup>13</sup> Col. 9, ll. 58-61.

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but only that the bridge is coated the palladium, gold and titanium/platinum/medical grade silicone layers. Accordingly, claim 28 as amended is patentable over Berrang.

For at least these reasons, Berrang fails to disclose each and every limitation set forth in independent claims 1, 19, 25, and 28, and claims 2, 4, 5, 7, 9, 18, 20, 22, and 24, which depend from one of independent claims 1, 19, 25, and 28. Reconsideration and withdrawal of the rejection of claims 1, 2, 4, 5, 7, 9, 18-20, 22, 24, 25, and 28 under U.S.C. § 102(b) is respectfully requested.

### **Engmark**

Engmark fails to teach or suggest each and every element of Applicant's independent claims 1, 6, and 19 as amended. With respect to the rejection of independent claims 1 and 19 under 35 U.S.C. § 102(e), the Office Action characterized the battery 20 and electrical module 28 as modules<sup>14</sup>, and reasoned that the battery 20 necessarily includes a housing and the circuit board of the electrical module 28 constituted a housing. The Office Action further characterized the housing 11 as an overmold that at least partially encapsulates the battery housing and the circuit board of the electrical module. While Applicant respectfully disagrees with the Office Action's interpretation of Engmark, Applicant has amended independent claims 1, 6, and 19 to further clarify that the first component of the overmold is substantially flexible.

Engmark does not describe any component of its housing 11 as being flexible, and accordingly, cannot anticipate claims 1, 6, and 19 as amended. Engmark only states that the housing 11 "is generally made of titanium or other biocompatible material."<sup>15</sup> Claims 2, 4, 18, 20, 22, and 24 depend from one of independent claims 1, 6, and 19. Reconsideration and withdrawal of the rejection of claims 1, 2, 4, 6, 18-20, 22, and 24 under U.S.C. § 102(e) is respectfully requested.

### **Disqualification of Engmark as Prior Art Under 35 U.S.C. § 103(c)**

In the Office Action, claims 5 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engmark. However, Applicant notes that Engmark is disqualified under 35

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<sup>14</sup> Office Action at page 7, item 15.

<sup>15</sup> Paragraph [0019].



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U.S.C. § 103(c) from being used in a rejection under 35 U.S.C. § 103(a) against the claims of the present application. As recognized in the Office Action, Engmark is prior art to the present application only under section § 102(e). Further, Applicant submits that, at the time the presently claimed invention was made, Engmark and the claimed invention were owned by the same person, or subject to a common obligation of assignment to the same person. The assignment of Engmark to Medtronic, Inc. was recorded on February 2, 2003 at reel/frame 013719/0147. The assignment of the present invention (U.S. Patent Application Serial No. 10/731,881) to Medtronic, Inc. was recorded on February 3, 2003 at reel/frame 013719/0147.

For at least this reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 5 and 28 under 35 U.S.C. § 103(a) based on Engmark.

#### New Claims:

Applicant has added claims 29-32 to the pending application. No new matter has been added by the new claims. Support for new claims 29-32 is found throughout Applicant's originally filed application, including paragraph [0022], and Applicant's paragraph [0035] as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. For example, the references fail to disclose or suggest a hermetic coupling member or a hermetic module housing, as recited by claims 29 and 30, respectively, or a rigid module housing, as recited by claim 31.

At column 11, line 55, Berrang teaches an epoxy that is used to coat and encapsulate the internal components of elements 2 and 3 (which the Office Action proposed are "modules"). Berrang specifically states that "[s]ince the epoxy, or other, encapsulation (over the ceramic substrate) does not provide a true hermetic or hermetic like seal," a gold coating is provided over the encapsulant surface.<sup>16</sup> FIG. 2 of Berrang shows the gold coating as overlying the entire device. Thus, if the epoxy of Berrang is a "housing" as the Office Action proposes (and Applicant traverses), it is clear that Berrang does not teach or suggest at least one hermetic module housing, as recited by new claim 30 or at least one housing comprising a rigid material, as recited by new claim 31.

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<sup>16</sup> Berrang at column 3, lines 59-65.

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### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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